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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ernst Heinz

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NOVAK DRUCE DELUCA + QUIGG LLP

1300 EYE STREET NW

SUITE 1000 WEST TOWER

WASHINGTON, DC 20005

EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,048	Applicant(s) HEINZ ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,8-10,13 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,8-10,13 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Priority

The translation of the German Priority (DE 100 30 976.2) document is not sufficient to perfect the foreign priority filing date because the translated copy was not filed together with a statement that the translation of the certified copy is accurate (See 37 CFR 1.55(a)(3) and MPEP 706.02(b)).

Applicants have responded to this by indicating that the requisite documentation will be provided pending client documentation.

In response, the examiner notes that until the requisite documentation is provided, foreign priority to the German priority document DE 100 30 976 2, with regard to prior art, cannot be granted.

Applicants assert that priority of the present invention, as currently amended, should be granted back to the US 09/347,531 (hereafter the '531 application). Applicants argue that the '531 application supports the organisms being fungi or plants in amended claim 1. With regard to the mol% ranges recited in the amended claims, applicants assert that the present application provides examples (in Table 2 on p. 6) which provide support for the claimed numerical ranges. With regard to the limitation "without substantially reducing the $\Delta 6$ -desaturase activity of the polypeptide", applicants assert that the application shows several variants of $\Delta 6$ -desaturase sequences and that said variants have $\Delta 6$ -desaturase activity and the skilled artisan would conclude that such variants would have substantially the same activity as the unchanged $\Delta 6$ -desaturase sequences.

Applicants' arguments have been considered but are not persuasive. The '531 application does not provide support for a process of preparing an unsaturated fatty acid in any fungus. The '531 application provides support for expressing an unsaturated fatty acid in a yeast. No explicit or implicit support can be found for the claimed method using any fungus (i.e. filamentous fungi, basidiomycetes, ascomycetes, etc.) in the '531 application.

With regard to support for the claimed mol% ranges, Table 2 on p. 6 of the '531 application does not appear to provide support for the claimed ranges. The numbers recited in the Table appear to be expressed in "Total fatty acids (%)" not in "mol%". None of the values presented in Table 2 support the claimed ranges of 1-80 or 1-60 or 1-40 mol% of unsaturated fatty acid based upon the total fatty acid content in the organism. If applicants are calculating mol% values based upon the data disclosed in Table 2, these calculations are not disclosed in the '531 application and it is unclear how the mol% ranges recited in the claims were derived.

With regard to the limitation "without substantially reducing the $\Delta 6$ -desaturase activity of the polypeptide", applicants disclose a single nucleic acid sequence encoding a single $\Delta 6$ -desaturase. Applicants also indicate that other $\Delta 6$ -desaturase enzymes are shown in the '531 application, but this is not accurate. The '531 application (p. 2, 2nd paragraph) merely recites:

Fig 1. shows the cDNA and the deduced amino acid sequence of the delta6-desaturase, another aspect of this invention are delta6 desaturases with a polypeptide sequence produced by insertion, deletion or substitution or a combination thereof of up to 40%, preferred up to 20% of all amino acids of Fig. 1. The change in the amino acid sequence can be easily produced by known methods of genetic engineering e.g. site

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directed mutagenesis. The biological activity (delta6 desaturase) can be checked by known assays e.g. those disclosed in this invention.

The '531 application does not disclose any nucleic acid sequences encoding $\Delta 6$ -desaturase enzymes other than the sequence of Fig. 1 and does not teach or suggest any variants **with substantially the same activity** of the sequence depicted in Fig. 1.

The assertion that the '531 application supports the teaching that the enzymes produced by insertion, deletion or substitution or a combination thereof of up to 40%, preferred up to 20% of all amino acids of Fig. 1 would result in enzymes with substantially the same activity as the unchanged enzyme, without any evidence to substantiate this assertion, is not persuasive.

Priority for the claimed invention is granted back to the filing date of the PCT/EP00/06223 application, filed 7/4/2000.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-9, 13 stand rejected and 18-21 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Girke et al.

35 USC 103(a) Rejections

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al. in view of Napier et al.

The above 35 USC 102(b) and 103(a) rejections are maintained for reasons of record in the previous Office Action and for reasons outlined below.

Newly presented claims 18-21 are newly rejected under 35 USC 102(b) over Girke et al. because Girke et al. teaches expression of PPDES6 (instant SEQ ID NO:1) in yeast and yeast cells comprising said sequence wherein said cells produce concentrations of unsaturated fatty acids that are at least 1 or 5% of total fatty acids.

Applicants argue that since the Girke reference was not published more than 1 year before the priority date of the present application, the above rejection under 35 USC § 102(b) is inapplicable. Applicants also assert that, for similar reasons, the Girke reference cannot be used as a basis for rejection under 35 USC § 103.

Applicants' arguments have been considered but are not persuasive. For the reasons stated above by the examiner with regard to priority for the instantly claimed invention, the Girke et al. reference is a document applied under 35 USC 102(b)

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 8, 18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new ground of rejection is necessitated by applicants' amendment filed 8/14/08.

Applicants have amended claim 1 and added claims 20-21 to recite a process for preparing an unsaturated fatty acid in a cultured fungus or yeast wherein the cultured organism contains from 1 to 80% or from 1 to 60% or from 1 to 40% of unsaturated fatty acid based on the total fatty acid content in the organism. The application, as filed, does not provide support for these limitations. On page 6 of the instant application, applicants recite a process for preparing an unsaturated fatty acid in an organism wherein unsaturated fatty acids are produced at levels of "[a]t least 1 mol%, preferably at least 3 mol%, especially preferably at least 4 mol%, very especially preferably at least 5 mol%, to be achieved in the organisms." In Table 1 on p. 27, the numbers appear to be expressed in "Total fatty acids (%)" not in "mol%". None of the values presented in Table 1 support the claimed ranges of 1-80 or 1-60 or 1-40 mol% of unsaturated fatty acid based upon the total fatty acid content in the organism. If applicants are calculating mol% values based upon the data disclosed in Table 1, these calculations

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are not disclosed in the instant application and it is unclear how the mol% ranges recited in the claims were derived. This is a NEW MATTER rejection.

Miscellaneous

In Claim 20, line 1, the phrase “wherein he cultured” should be redrafted as -- wherein **the** cultured-- so as to remove any ambiguity in the claim.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low, Ph.D., can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 11, 2008

/David Guzo/
Primary Examiner
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